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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,997	12/24/2003	Yukio Nihei	245553US0CONT	9427
22850 7590 03/13/2007 OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER GEMBEH, SHIRLEY V	
			ART UNIT	PAPER NUMBER
			1614	
SHORTENED STATUTORY PERIOD OF RESPONSE		NOTIFICATION DATE	DELIVERY MODE	
3 MONTHS		03/13/2007	ELECTRONIC	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 03/13/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/743,997

Applicant(s)

NIHEI ET AL.

Examiner

Shirley V. Gembeh

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
 Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters; prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,11-19,22-26,29,30,32-42 and 44-48 is/are pending in the application.
- 4a) Of the above claim(s) 16-19 and 22-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5,11-14,29,30,32-37, 39-40 and 41, 44-47 is/are rejected.
- 7) ☒ Claim(s) 15, 38, 42 and 48 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The response filed **11/22/06** presents remarks and arguments to the office action mailed **8/22/06**. Applicants' request for reconsideration of the rejection of claims in the last office action has been considered.

Applicants' arguments, filed, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of Claims

Claims 1, 5, 11-15, 29, 30, 32-42, and 44-48 are examined.

Claims 2-4, 6-10, 20-21, 27-28, 31, 43 and 49 are cancelled.

Claims 16-19 and 22-26 are withdrawn.

Claim Objections

Claims 15, 38, 42 and 48 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Allowable Subject Matter

The indicated allowability of claims 29, 33 and 34 is withdrawn in view of the newly discovered reference(s) to Nihei et al Jpn. J. Cancer Res. 90, 1016-1025 Sept.1999. Rejections based on the newly cited reference(s) follow.

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The indicated allowability of claims 29, 33 and 34 is withdrawn in view of the newly discovered reference(s) to Nihei et al Jpn. J. Cancer Res. 90, 1016-1025 Sept.1999. Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 29-30, 32, 33, 39, 40 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Nihei et al. Jpn. J. Cancer Res. 90, 1016-1025 Sept.1999.

The Nihei et al. teach the combination of dexamethasone (an anti-inflammatory agent) with AC 7700 a tubulin polymerizationm-inhibitory active substance as in the instant claims 1, 32, 39 and 44, wherein the dexamethsone is dexamethasone as in claim 5 (see page 1023, lft col. last five lines). Please note that MPEP 2112.01"Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658

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(Fed. Cir. 1990). Nihei et al. teach treating human carcinogens, thus indicative that the treatment is meant for a human as in claim 40.

With regards to claims 29-30 and 33 the reference teaches the composition comprises dexamethasone with AC 7700 a tubulin polymerization-inhibitory active substance.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 1, 5, 11-13, 14, 39-40, 41, 44-45 and 46-47 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Hori et al. Med. Sci Monit taken with Fex et al. US 3,732,260 in view of Nihei et al. Jpn. J. Cancer Res. 90, 1016-1025 Sept.1999.

Hori et al. teach AC 7700 ((Z)-N-[2-methoxy-5[2(3,4,5-trimethoxyphenyl)vinyl]phenyl]-L-serinamide) (see abstract) as an anti -cancer agent with anti-cancer activity as in claim 1 in part and 11 wherein the unit dosage of the AC 7700 is 10 mg/kg in a unit dosage (see page 28 highlighted) as in claim 14. 10 mg/kg is within the claim limitation for example if weight of the patient is 50 then the unit dose is 500 mg. Please note that AC 7700 is a combrestatin, thus making claims 39, 44 and obvious variation.

Fex et al. teach administration of steroidal compounds with other pharmaceutically active agents (see col. 4 lines 33+) as in claim 1, wherein the unit dose of the steroid is 10-100 mg (see col. lines 33-61). Also Fex teaches that the compounds (steroids) can be used with treatment with anti-cancer agent thus including any anti-cancer agent thereof (see col. 2 lines 15+) thus simultaneously or sequentially as adjuvant therapies are administered either together as a combination, separately, or sequentially. This is a well known fact in the art of adjuvant therapy and one of ordinary skill in the art would have known how to administer the drugs.

The Nihei et al. teach the combination of dexamethasone (an anti inflammatory agent) with AC 7700 a tubulin polymerizationm-inhibitory active substance (see page 1023, 1st col. last five lines). Please note that MPEP 2112.01"Products of identical chemical composition can not have mutually exclusive properties." A chemical

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composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Nihei et al. teach treating human carcinogens, thus indicative that the treatment is meant for a human.

Although the Hori et al. did not teach using an adjuvant therapy, one skilled in the art would have being motivated to combine the teachings of Hori et al. with that of Fex et al. and Nihei to result in the claim invention of the instant subject matter. The Nihei et al. teaches the combination of both drugs, one of ordinary skill in the art would have been motivated to make and use the claimed invention at the time the claim invention was made because the cited references teaches so and nothing un-obvious is seen in doing so.

Claims 29-30, 32, 33-34 and 35-37 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Hori et al. Med. Sci Monit taken with Fex et al. US 3,732,260 in view of Nihei et al Jpn. J. Cancer Res. 90, 1016-1025 Sept.1999 as applied above.

The rejections of above claims 1, 5, 11-13, 14, 39-40, 41, 44-45 and 46-47 are applied to claims 29-30, 32, 33-34 and 35-37 because, in other for the method to be practiced the composition is used.

Thus, the claimed invention was prima facia obvious to make and use at the time it was made.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SVG
2/10/07

Ardin H. Marschel 3/4/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER

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NEWS	24	JAN 29	PHAR reloaded with new search and display fields
NEWS	25	JAN 29	CAS Registry Number crossover limit increased to 300,000 in multiple databases
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NEWS	27	Feb 15	PATDPASPC enhanced with Drug Approval numbers
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NEWS	30	Feb 26	MEDLINE reloaded with enhancements
NEWS	31	Feb 26	EMBASE enhanced with Clinical Trial Number field
NEWS	32	Feb 26	TOXCENTER enhanced with reloaded MEDLINE
NEWS	33	Feb 26	IFICDB/IFIPAT/IFIUDB reloaded with enhancements
NEWS	34	Feb 26	CAS Registry Number crossover limit increased from 10,000 to 300,000 in multiple databases

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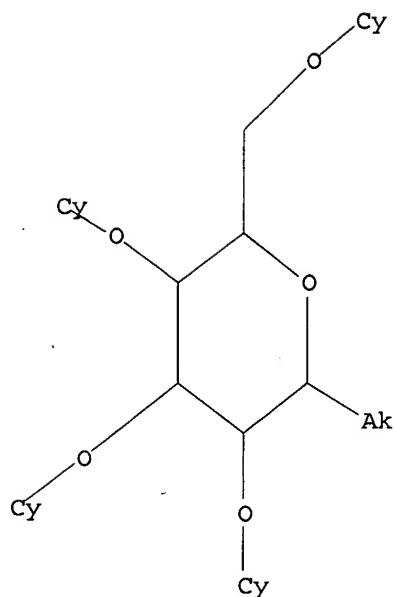
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L3 0 SEA SSS FUL L1